



PATENT

Attorney Docket No. BBC-0377

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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TECH CENTER 1600/290

IN RE APPLICATION OF:
H. Albrecht, et al.

APPLICATION NO.: 09/284,424

FILED: April 9, 1999

FOR: Aspartate Ester Inhibitors
of Interleukin-1 β Converting
EnzymeEXAMINER: L. Maier
ART UNIT: 1623I hereby certify under 37 CFR 1.8(a) that this
correspondence is being deposited with the United
States Postal Service as first class mail with
sufficient postage on the date indicated below and
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Patents, Washington, D.C. 20231.

Date of Deposit July 23, 2001

Lisa Rasmussen
LISA RasmussenAssistant Commissioner for Patents
Washington, D.C. 20231

Sir:

REPLY UNDER 37 C.F.R. §1.116

This is in reply to the Office Action mailed February 22, 2001, which action has been made final, the period for response thereto having been set to expire on May 22, 2001, which has been extended by two months to expire on July 22, 2001, pursuant to the Petition for Extension of Time filed herewith. However, since July 22, 2001, falls on a Sunday, the instant Reply is being timely filed on July 23, 2001, pursuant to 37 C.F.R. §1.7.

REMARKS

Reconsideration of the Office Action mailed February 22, 2001, (hereinafter "instant Office Action"), and withdrawal of the rejection of claims 1-8, 10-30, 34, 38-41 and 44-51 are respectfully requested.

In the instant Office Action, claims 1-8, 10-30, 34, 38-41 and 44-51 are listed as pending and claims 1-8, 10-30, 34, 38-41 and 44-51 are listed as rejected.

The Examiner has rejected claim 1 under 35 U.S.C. §112, first paragraph, for the reasons stated at page 2 of the instant Office Action. Applicants maintain the traversal of this rejection. Applicants gratefully acknowledge the Examiner's agreement that *ipsis verbis* disclosure is not necessary to satisfy the written description requirement. This is also supported by the cases that

were previously cited in support of Applicants' argument. In each of those cases, there was no explicit (i.e., *ipsis verbis*) support for the amendments that avoided the prior art that was cited in the respective cases. That being agreed to, the other kind of support mentioned by the Examiner is implicit support. However, it appears that the Examiner has taken implicit support to a degree that is not recognized by the courts in the cases cited by Applicants. That is, the Examiner requires implicit support "for each and every limitation in the amendment". Applicants respectfully disagree with the Examiner's requirement for such specificity. The cited cases do not stand for such a proposition. If the Examiner disagrees with Applicants reading of the cited cases, Applicants respectfully request the Examiner to point out in the cases where the Examiner's allegation is supported.

Rather, it is Applicants' submission that one could observe in the cited cases that the implicit support for the amended, narrower claims come from the proposition that the initially claimed genus encompassed the narrower amended claims. Analyzed from a statutory viewpoint, the literal language of 35 U.S.C. §112, first paragraph, states "...subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention". It is clear that Applicants "had possession of the claimed invention" "at the time the application was filed" because the Examiner has acknowledged that the original scope of claim 1 was enabled. Therefore, it follows that a subset of compounds of the genus (i.e., the amended claim 1) is also enabled. This must be the result, otherwise the patents in the cited cases would not have been allowed to overcome the issue, which is the same issue as in Applicants instant case.

It is clear from the foregoing rationale that Applicants amended claim 1 meets the requirement of 35 U.S.C. §112, first paragraph. Accordingly, the rejection of claim 1 under 35 U.S.C. §112, first paragraph, is obviated and should be withdrawn.

Claims 1-8, 10-31, 34, 38-41, and 44-50 stand rejected under 35 USC 103(a), based on the Examiner's allegation that they are unpatentable over Prasad et al in view of Mjalli et al, Dolle et al. (EP 0 623 592), and Chapman et al. (U.S. Patent 5,430,128). The Examiner alleges that these references teach potent ICE inhibitors with the same compound core and a variety of modifications on either end, and that one of ordinary skill in the relevant art would have a

reasonable expectation of success of obtaining the instant claimed compounds in view of the combination of references.

Applicants respectfully maintain that the Examiner has failed to establish a *prima facie* case of obviousness with respect to the rejected claims. Specifically, Applicants respectfully contend that the Examiner has not made an adequate showing on the record of the three required elements of a *prima facie* case of obviousness, namely: 1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine their teachings; 2) a reasonable expectation of success in a program based on said combined teachings; and 3) that the prior art references teach or suggest all the limitations of the rejected claim. See MPEP § 2143.

First, the Applicants respectfully maintain that a *prima facie* case of obviousness has not been established because the Examiner has not pointed out any portions of the cited references that would lead one of ordinary skill in the relevant art to conclude that a combination of their teachings would be desirable. See Ex parte Skinner, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986) (holding that when the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper). Further, Applicants respectfully submit that even though the cited references teach specific ICE inhibitors, none of the references explicitly or implicitly suggests that particular structural features of the distinct ICE inhibitors should be combined in the specific pattern required to arrive at the compounds encompassed by Applicants' claims. See In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (holding that the teaching or suggestion to make the claimed combination must be found in the prior art); and Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985) ("To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the [E]xaminer must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references"). For example, Applicants respectfully contend that the cited references do not teach that a particular first element of the ICE inhibitors of one reference should be combined with a particular second element of the ICE inhibitors of another reference to provide compounds within the scope of Applicants' claims. In particular, Prasad et al do not suggest modifying R² of

the instant invention, nor does it suggest modifying R¹ to include other substituents disclosed in the instant invention.

Second, Applicants respectfully maintain that a *prima facie* case of obviousness has not been established because the Examiner has failed to show that one of ordinary skill in the relevant art would have had a reasonable expectation of success in a program focused on discovering ICE inhibitors among the claimed compounds. Importantly, the reasonable expectation of success with the claimed subject matter must be found in the prior art, *not* in the Applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added). While the cited art teaches various ICE inhibitors, Applicants respectfully contend that the various biological activities disclosed therein would not have led one of ordinary skill in the relevant art to conclude, at the time the instant application was filed, that she would have a reasonable expectation of success in developing ICE inhibitors based on the claimed compounds.

Finally, Applicants respectfully maintain that a *prima facie* case of obviousness has not been established because the art cited by the Examiner does not teach all the claim limitations of Applicants' claims. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). For example, Applicants respectfully assert that the rejected claims encompass compounds comprising substituents at the R¹ position (with reference to the Applicants' Formula I), e.g., acyl, sulfonyl, dicarbonylcycloalkyl, and dicarbonylbicycloalkyl, that are not taught by any of the art cited by the Examiner. In contrast, the art cited by the Examiner only teaches compounds comprising substituents at the R¹ position (with reference to the Applicants' Formula I) selected from the group consisting of BnOC(O)- and small oligopeptides. Accordingly, Applicants respectfully contend that the references cited by the Examiner do not teach all the claim limitations of Applicants' claims.

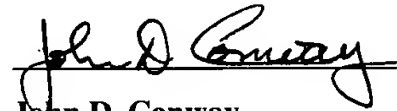
Accordingly, Applicants respectfully request the withdrawal of the rejections of claims 1-8, 10-31, 34, 38-41, and 44-50 under 35 USC 103(a) based on Prasad et al, in view of Mjalli et al, Dolle (EP '592) and Chapman ('128).

Based upon the foregoing, Applicants believe that claims 1-8, 10-31, 34, 38-41, and 44-50 are in condition for allowance. Prompt and favorable action is earnestly solicited.

If the Examiner believes that there are any issues that could be resolved in a telephone conference, Applicants invite the Examiner to call Applicants' undersigned attorney.

Respectfully submitted,

Date: July 23, 2001



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